

§ 74.2101

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of D&C Black No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[72 FR 33666, June 19, 2007]

§ 74.2101 FD&C Blue No. 1.

(a) *Identity*. The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[p-[ethyl(m-sulfobenzyl)amino]-α-(o-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](m-sulfobenzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[p-[ethyl(p-sulfobenzyl)amino]-α-(o-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](p-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[p-[ethyl(o-sulfobenzyl)amino]-α-(o-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](o-sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl]benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl]benzenesulfonic acid and 2-[(ethylphenylamino)methyl]benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

(b) *Specifications*. (1) The color additive FD&C Blue No. 1 shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions*. (1) FD&C Blue No. 1 may be safely used for color-

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ing cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification*. All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 58 FR 17511, Apr. 5, 1993; 59 FR 7638, Feb. 16, 1994]

§ 74.2104 D&C Blue No. 4.

(a) *Identity and specifications*. The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).

(b) *Uses and restrictions*. D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification*. All batches of D&C Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

(a) *Identity*. The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)-azo]-2,4-dihydroxyphenyl]azo]-benzene sulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications*. D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.

Water-insoluble matter, not more than 0.2 percent.